

September 14, 2018

Via EDGAR

United States Securities and Exchange Commission
Division of Corporate Finance
Office of Healthcare and Insurance
Washington, D.C. 20549

Re: Processa Pharmaceuticals, Inc.
Form 10-K for the Fiscal Year Ended December 31, 2017
Filed April 16, 2018 (as amended on April 17, 2018)

Form 10-Q for the Quarterly Period Ended March 31, 2018 Filed May 21, 2018
File No. 333-184948

Dear Ladies and Gentlemen,

On behalf of Processa Pharmaceuticals, Inc. ("the Company" or "Processa"), we are responding to the comments of the staff of the Division of Corporate Finance, Office of Healthcare and Insurance of the United States Securities and Exchange Commission set forth in your letter to Dr. David Young, Processa's Chief Executive Officer, dated August 28, 2018. Your comments are reproduced below in bold, followed in each case by our response on behalf of the Company.

Annual Report on Form 10-K/A

Item 1. Business, page 3

1. **Please expand your disclosure to explain how you identified NL and RIF in head and neck cancer patients as indications for which PCS-499 may result in clinical efficacy. Please also explain in terms a lay reader would understand what you mean that your product candidate is an "analog of an active metabolite," and disclose the drug that is already approved, the indication for which it was approved, and clarify whether it was approved by the FDA or another regulatory authority.**

AUSTIN	DETROIT	MEXICO CITY	SACRAMENTO	TAMPA
BOSTON	HOUSTON	MIAMI	SAN DIEGO	WASHINGTON, D.C.
CHICAGO	JACKSONVILLE	MILWAUKEE	SAN FRANCISCO	BRUSSELS
DALLAS	LOS ANGELES	NEW YORK	SILICON VALLEY	TOKYO
DENVER	MADISON	ORLANDO	TALLAHASSEE	

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Response

In future filings, the Company will expand its disclosure to (1) explain, in terms a lay reader would understand, that PCS-499 has a structure similar to that of an approved drug, but differing from it with respect to a certain functional component of the molecule, (2) disclose the name and approved indications of the FDA approved analog and (3) explain the process of identification of NL and RIF in head and neck cancer patients as indications for which PCS-499 may result in clinical efficacy.

2. **We note your statements that your lead product candidate compound has been shown to be “safe and tolerable,” and “with a trend toward efficacy in diabetic nephropathy.” Safety and efficacy determinations are solely within the authority of the FDA and comparable regulatory authorities. Please confirm that in future filings, you will revise your disclosures to remove all references about your product candidate’s safety and efficacy, including statements regarding preliminary indications of efficacy (whether for your planned indication or other indications).**

Response

In future filings, the Company will revise its disclosure to remove all references to PCS-499 as being effective, including removal of references to preliminary indications of efficacy. Furthermore, the Company will make similar revisions regarding the safety of PCS-499.

3. **We refer to your statement that your business strategy is to identify drugs that can be “quickly” developed within “2-4 years.” Please expand your disclosure to discuss the regulatory pathways you intend to pursue for your lead and other product candidates and their requirements. If you intend to rely on studies of third parties in seeking approval for PCS-499, identify the parties who performed the studies.**

Response

In future filings, the Company will expand the description of its business model to explain the justification for identification of drugs that can be quickly developed within 2-4 years.

Intellectual Property, page 4

4. **Please revise your disclosure to discuss the patents you have licensed relating to your product candidate, including the jurisdiction, the type of patent protection (e.g., composition of matter, use, or process), and the patent expiration dates.**
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Response

In future filings, the Company will expand its intellectual property disclosure to include the quantity, jurisdiction, type and expiration dates of its licensed patents.

Asset Acquisitions by Licensing Agreements or Company Acquisitions, page 5

5. **Please revise this section to discuss the material terms of your CoNCERT agreement and any other material license or collaboration agreements you may have at the time, including the nature and scope of the intellectual property transferred, each parties' duties and obligations, the term of the agreement, the royalty term, the royalty rates, the termination provisions and any potential milestone payments. We also note the discussion on page 68 concerning CoNCERT's right to have one Board observer attend Promet's Board meetings. If CoNCERT has that right with respect to Processa's Board meetings, please discuss it here.**

Response

In future filings, the Company will expand its disclosure to include the material terms of the Company's license agreement with CoNCERT Pharmaceuticals, Inc. Please note that CoNCERT Pharmaceuticals, Inc. does not have, and never has had, any board observer rights with the Company as such rights expired upon the assignment of the license agreement from Promet to the Company. The reference to board observer rights has been removed from the notes to the financial statements.

Item 1A. Risk Factors, page 9

6. **Please add a risk factor to discuss the material risks associated with the fact that you do not have an audit or compensation committee, and that (according to the disclosure in your Registration Statement on Form S-1 filed on July 30, 2018) only one of your directors is independent.**

Response

In future filings, to the extent still applicable, the Company will include a new risk factor to discuss that the Company does not have an audit committee or compensation committee and that the Company does not have a majority of independent directors.

We depend on rights to certain pharmaceutical compounds that are or will be licensed to us. , page 19

7. **We note your disclosure in this risk factor that your drugs are in-licensed from other biotech or pharmaceutical companies and that you do not own the patents that underlie these licenses. Please specify the product candidates that you are referring to as well as the patents and the biotech or pharmaceutical companies from whom you have licensed such patents.**

Response

In future filings, the Company will expand its disclosure to specify the Company's licensed product candidates as well as the patents and biotech or pharmaceutical companies from whom the patents have been licensed.

There may be limitations on the effectiveness of our internal controls. page 26

8. **We note your disclosure that you experienced a cybersecurity breach that resulted in a fraud loss where the probability of recovery of the loss is remote. Please disclose when the breach occurred and quantify the loss in this risk factor.**

Response

In future filings, the Company will revise its disclosure to include the date and dollar value of the loss suffered by the Company as a result of the cybersecurity breach.

Item 10. Directors, Executive Officers and Key Employees. page 73

9. **Please revise your disclosure to explain how Dr. Young helped Questcor transition from being nearly bankrupt to having a valuation of over \$5 billion in his role as an independent director.**

Response

In future filings, the Company will revise its disclosure to explain Dr. Young's role as an independent director and subsequently as the Chief Scientific Officer of Questcor in transitioning Questcor from nearly a bankrupt company to ultimately the sale of the company for over \$5 billion.

Form 10-Q for the Quarterly Period Ended March 31, 2018**Notes to Consolidated Financial Statements****Note 2 - Intangible Asset, page 12**

10. You disclose that the \$11 million intangible asset recorded as of March 31, 2018 includes \$3 million of costs capitalized to record an offset to a deferred tax liability related to the exercise of your option to acquire an exclusive license from CoNCERT related to patent rights and know-how to develop and commercialize compounds and products for CTP-499. You also disclose on page 15 that this deferred tax liability was created when CoNCERT sold its license and know-how to you for stock in a transaction under Section 351 of the Internal Revenue Code (Section 351 transaction) which treats the acquisition of the license and know-how as a tax-free exchange. Please provide us with a detailed analysis explaining how you determined that this transaction met the requirements to be considered a tax-free exchange under Section 351. In this regard, it would appear that under Section 351 an exchange would be considered tax free if (a) the property was exchanged solely for stock of the company and (b) immediately after the exchange the transferor controlled the company via 80% or more ownership of voting stock. Based on your beneficial ownership table on page 49 of your Form S-1 filed on July 30, 2018, it appears that CoNCERT owns only 5.4% of your outstanding shares.

Response

In October 2017, Promet Therapeutics LLC., a Delaware limited liability company ("Promet"), and Processa Pharmaceuticals, Inc., formerly known as Heatwux Inc. ("Processa") entered into an Asset Purchase Agreement (the "APA"), pursuant to which Processa acquired, in an Internal Revenue Code Section 351 tax-free contribution of assets solely for over 80% of the voting stock of Processa (the "Section 351 Transaction") by Promet, all of the properties, rights and assets, including liabilities and commitments, owned by Promet, directly or indirectly, in whole or in part, of every type and description, real, personal or mixed, tangible and intangible, wherever located and whether or not reflected on the books of Promet (the "Contributed Assets", and the transaction as a whole the "Promet/Processa Transaction").

Included in the Contributed Assets, Promet also transferred and contributed all, rights, title and interest under a certain option and license agreement with CoNCERT Pharmaceuticals, Inc. ("CoNCERT") with respect to certain know-how, patent rights and compounds developed or obtained by CoNCERT (the "CoNCERT Assets") for which voting securities of Processa were expressly contemplated to be issued as part and parcel with, and integrated into, the Section 351 transaction to CoNCERT because all Contributed Assets including the CoNCERT Assets were contemplated to be integral to each other and were considered to be an integrated undertaking as the primary target, purpose and reason for the overall transaction itself.

The APA was executed pursuant to authority granted by a “Unanimous Written Consent of the Board of Directors of Processa” dated in September 2017 which demonstrates that both Promet and Processa contemplated and intended that the Asset Purchase and the CoNCERT Assets were integral to one another and the recipients of equity, being Promet and CoNCERT, in connection therewith will control the Corporation for purposes of Section 351 and Section 368(c) in that they will own (i) at least 80% of the total combined voting power of all classes of stock entitled to vote and (ii) at least 80% of the total number of shares of all other classes of stock of the corporation. The Unanimous Written Consent demonstrates the transfer of all of Promet’s assets, including but not limited to the transfer of any and all rights relating to the CoNCERT’s Assets to Processa was meant to be an integrated transaction for tax purposes.

The Company structured, intended and expressly accepted that the transaction of Promet contributing its and the CoNCERT Assets solely for stock qualified for Section 351 treatment given that at the conclusion of the events both Promet and CoNCERT controlled more than 80% of the corporation immediately after the transactions were concluded. The 5.4% of the outstanding shares that were issued to CoNCERT were part of the overall 90% of the shares (more than the 80% “control” percentage pursuant to Code Section 368(c)) of Processa voting stock acquired as part of an integrated Section 351 Transaction whereby Processa acquired the Contributed Assets.



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If you should have any additional questions, please contact me at (904) 633-8913.

Sincerely,

/s/ Michael B. Kirwan

Michael B. Kirwan

MBK:arm

cc: Dr. David Young, Chief Executive Officer
John J. Wolfel, Esq.
Neda A. Sharifi, Ph.D., Esq.
